

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant | : Sharon Mi Lyn Tan | Art Unit | : 3763 |
| Serial No. | : 10/690,436 | Examiner | : LoAn H. Thanh |
| Filed | : October 22, 2003 | Conf. No. | : 3696 |
| Title | : CATHETER WITH A SIDEARM FOR DELIVERY OF ANTIMICROBIAL AGENTS TO PREVENT INFECTION | | |

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Appellant previously filed a Notice of Appeal on March 2, 2007. Please charge the Appeal Brief fee of \$500 and apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 01194-513001.

(1) Real Party in Interest

The real party in interest in the above application is BOSTON SCIENTIFIC SCIMED, INC., a corporation of Minnesota, having a place of business at One Scimed Place, Maple Grove, MN 55311-1566.

(2) Related Appeals and Interferences

The Appellant is not aware of any appeals or interferences related to the above-identified patent application.

(3) Status of Claims

This is an appeal from the rejections of claims 1-26 provided by the Examiner in a Final Office Action dated January 9, 2007. Claims 1-26 have been twice rejected and are presented for appeal.

(4) Status of Amendments

All amendments have been entered. Appellant previously filed a Notice of Appeal on March 2, 2007.

(5) Summary of Claimed Subject Matter

The invention relates to an apparatus and method for prevention of nosocomial infections associated with catheters.¹

In one aspect, the invention features an infection management system that includes a catheter with a lumen extending therethrough, a side-arm tube through which a lumen communicates with the catheter lumen extending laterally from a side of the catheter,² a one-way valve which prevents fluid flow from the catheter lumen through the side-arm tube lumen without preventing fluid flow through the catheter lumen,³ an antimicrobial agent bearing intervention device configured to be inserted through the side-arm tube lumen and the one-way valve into the catheter lumen,⁴ and a cap coupled to the antimicrobial agent-bearing intervention device.⁵ The cap is configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.⁶ The side-arm tube is located in a region of the catheter which remains outside a patient's body.⁷

¹ Specification page 1, lines 6-7.

² Id., page 3, lines 19-22.

³ Id., page 3, lines 22-23.

⁴ Id., page 3, lines 28-31.

⁵ Id., page 6, lines 26-28, Fig. 2, and Fig. 3.

⁶ Id., page 6, lines 29-31.

⁷ Id., page 3, lines 23-25.

In another aspect, the invention features an infection management method in which such a system is provided.⁸ In still another aspect, the invention features a catheter that includes a main catheter tube with a lumen extending therethrough, a side-arm tube through which a lumen communicates with the lumen of the main catheter extending laterally from a side of the main catheter tube, and all the other components of the system except the catheter and the side-arm tube of the system.⁹

Claims 1, 10 and 19 are the only independent claims. These claims read as follows:

1. An infection management system, comprising:
a catheter with a lumen extending therethrough;
a side-arm tube extending laterally from a side of the catheter, wherein the side-arm tube is located in a region of the catheter which remains outside a patient's body, and
a lumen through the side-arm tube communicates with the catheter lumen;
a one-way valve which prevents fluid flow from the catheter lumen through the side-arm tube lumen without preventing fluid flow through the catheter lumen;
an antimicrobial agent bearing intervention device configured to be inserted through the side-arm tube lumen and the one-way valve into the catheter lumen; and
a cap coupled to the antimicrobial agent-bearing intervention device, the cap being configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.

10. An infection management method, comprising:
providing a catheter with a lumen extending therethrough, a side-arm tube extending laterally from a side of the catheter, wherein the side-arm tube is located in a region of the catheter which remains outside a patient's body and a lumen through the side-arm tube communicates with the catheter lumen, and a one-way valve located to prevent fluid flow from the catheter lumen through the side-arm tube lumen without preventing fluid flow through the catheter lumen; and
inserting an antimicrobial agent bearing intervention device a cap through the side-arm tube and the one way valve into the catheter lumen,

⁸ Id., page 4, lines 24-31 and page 8, lines 4-14.

⁹ Id., page 5, lines 27-30, page 6, lines 6-14, and lines 26-31.

wherein the cap is coupled to the antimicrobial agent-bearing intervention device, and the cap is configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.

19. An anti-infection catheter, comprising
a main catheter tube with a lumen extending therethrough;
a side-arm tube extending laterally from a side of the main catheter tube,
wherein
the side-arm tube is located in a region of the catheter which remains
outside a patient's body, and
a lumen through the side-arm tube communicates with the lumen of the
main catheter tube;
a one-way valve adapted to permit passage of an antimicrobial agent
bearing intervention device between the side-arm tube lumen and the main
catheter tube lumen while preventing fluid flow from the main catheter tube
lumen through the side-arm tube lumen, wherein the one-way valve does not
prevent fluid flow through the main catheter tube lumen; and
a cap coupled to the antimicrobial agent-bearing intervention device,
wherein the cap is configured so that a user can handle the antimicrobial
agent-bearing intervention device without directly contacting the antimicrobial
agent-bearing intervention device.

(6) Grounds of Rejection to be Reviewed on Appeal

Claims 1-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,371,944 ("Liu") in view of U.S. Patent No. 5,588,443 ("Davidson"), and further in view of U.S. Patent No. 5,413,561 ("Fischell") or U.S. Patent No. 5,357,961 ("Fields").

(7) Argument

For the purposes of this appeal only claims 1-26 stand or fall together. Claims 1, 10, and 19 are the only independent claims and thus are representative of this group of claims.

**Claims 1-26 are allowable over Liu in view of
Davidson, and further in view of Fischell.**

The Examiner rejected claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Liu in view of Davidson, and further in view of Fischell. In particular, the Examiner stated "Liu [] disclose[s] a system for use in the body comprising a catheter 7 [having] a side arm [and] a lumen through the side arm 9" (Office Action mailed January 9, 2007, p. 2.) But, rather than being a catheter, Liu's element 7 is a needle. (See, e.g., Liu col. 2, lines 47-50.) As one skilled in the art would understand, a needle of the type disclosed by Liu is not a catheter. Indeed, when characterizing the manner in which a catheter is commonly disposed within a blood vessel (Id., col. 1, lines 26-29):

A guide wire is passed through a needle which has been inserted into the blood vessel. A catheter is then threaded on the guide wire into the blood vessel.

Without question, this demonstrates that Liu's needle is not a catheter.

In addition, while the Examiner conceded that "Liu [] and Davidson in combination is silent to a cap coupled to the guidewire/intervention device," (Office Action mailed January 9, 2007, p. 2.), the Examiner concluded (Id., p. 3):

It would have been obvious to one of ordinary skill in the art to modify the device of Liu [] in view of Davidson with a cap as taught by Fischell [] in order to provide a handle or sealing end to prevent contamination or leaking of fluids at the proximal end.

However, without conceding that such an interpretation of Liu is appropriate, to the extent that Liu's second entry 4 can be interpreted as being a side arm, Liu discloses that his second entry (Liu col. 3, lines 15-17):

has a one-way valve (5), such as a flap valve, which prevents backup of fluids such as blood through said second entry.

Liu further discloses that his second entry (Id. col. 2, lines 53-59):

... is divided by a valve (5) so that fluid (blood) flowing through the needle and common passage can not escape through the distal entry of the arm. Though the valve prevents flow of blood back through distal end of the arm, it will allow a guide wire to enter into the lumen of the needle already in place in the blood vessel.

In addition, Liu discloses (Id. col. 4, lines 7-9):

Using the device as taught, it is possible to minimize exposure to both the patient and the care-giver to infections.

Thus, after reading Liu, one skilled in the art would not have been motivated to modify Liu's device by adding a cap to his second entry "to prevent contamination or leaking of fluids at the proximal end."

Thus, none of Liu, Davidson and Fischell, alone or in combination, discloses or suggests the subject matter covered by claims 1-26. There is no suggestion to combine these references to provide this subject matter, and, even if the references were combined, the result would not be the subject matter covered by claims 1-26. Appellant therefore requests reconsideration and withdrawal of the rejections of claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Liu in view of Davidson and further in view of Fischell.

Claims 1-26 are allowable over Liu in view of Davidson, and further in view of Fields.

The Examiner also rejected claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Liu in view of Davidson, and further in view of Fields. However, as noted above, contrary to the Examiner's characterization, Liu does not disclose the catheter/side-arm tube combination required by claims 1-26. None of Liu, Davidson and Fields, alone or in combination, discloses or suggests the subject matter covered by claims 1-26. There is no suggestion to combine these references to provide this subject matter, and, even if the references were combined, the result would not be the subject matter covered by claims 1-26. Appellant therefore requests reconsideration and withdrawal of the rejection of claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Liu in view of Davidson and further in view of Fields.

Conclusion

Appellant submits, therefore, that claims 1-26 are allowable over the cited art. Therefore, the Examiner erred in rejecting Appellant's claims and should be reversed.

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Applicant : Sharon Mi Lyn Tan
Serial No. : 10/690,436
Filed : October 22, 2003
Page : 8 of 16

Attorney's Docket No.: 01194-513001 / 03-045

Respectfully submitted,

Date: June 21, 2007

/Sean P. Daley/

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Appendix of Claims

1. (Previously presented) An infection management system, comprising:
a catheter with a lumen extending therethrough;
a side-arm tube extending laterally from a side of the catheter, wherein
the side-arm tube is located in a region of the catheter which remains outside a patient's
body, and
a lumen through the side-arm tube communicates with the catheter lumen;
a one-way valve which prevents fluid flow from the catheter lumen through the side-arm
tube lumen without preventing fluid flow through the catheter lumen;
an antimicrobial agent-bearing intervention device configured to be inserted through the
side-arm tube lumen and the one-way valve into the catheter lumen; and
a cap coupled to the antimicrobial agent-bearing intervention device, the cap being
configured so that a user can handle the antimicrobial agent-bearing intervention device without
directly contacting the antimicrobial agent-bearing intervention device.
2. (Original) The infection management system of claim 1, wherein the catheter
comprises a catheter body and an extension joined to a proximal end of the catheter body, the
extension having a lumen extending longitudinally therethrough and in communication with the
catheter lumen, and the side-arm tube extends laterally from the catheter extension.
3. (Original) The infection management system of claim 1, wherein the antimicrobial
agent-bearing intervention device comprises an antimicrobial agent-bearing rod.

4. (Original) The infection management system of claim 3, wherein the antimicrobial agent-bearing rod comprises a flexible polymer rod.

5. (Original) The infection management system of claim 1, wherein the antimicrobial agent is iodine.

6. (Previously presented) The infection management system of claim 1, wherein a region of the catheter comprises a material which permits passage of the antimicrobial agent released from the antimicrobial agent-bearing intervention device from the catheter lumen to an outer surface of the catheter.

7. (Previously presented) The infection management system of claim 3, wherein the cap is adapted to seal a proximal end of the side-arm tube after the antimicrobial agent-bearing rod is inserted into the catheter lumen.

8. (Original) The infection management system of claim 7, wherein the cap has a threaded portion that cooperates with a threaded portion on the side-arm tube.

9. (Original) The infection management system of claim 7, wherein the cap is a stopper sized to frictionally engage and seal the proximal end of the side-arm tube.

10. (Previously presented) An infection management method, comprising:

providing a catheter with a lumen extending therethrough, a side-arm tube extending laterally from a side of the catheter, wherein the side-arm tube is located in a region of the catheter which remains outside a patient's body and a lumen through the side-arm tube communicates with the catheter lumen, and a one-way valve located to prevent fluid flow from the catheter lumen through the side-arm tube lumen without preventing fluid flow through the catheter lumen; and

inserting an antimicrobial agent-bearing intervention device a cap through the side-arm tube and the one-way valve into the catheter lumen,

wherein the cap is coupled to the antimicrobial agent-bearing intervention device, and the cap is configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.

11. (Original) The infection management method of claim 10, wherein the catheter comprises a catheter body and an extension joined to a proximal end of the catheter body, the extension having a lumen extending longitudinally therethrough and in communication with the catheter lumen, and the side-arm tube extends laterally from the catheter extension.

12. (Original) The infection management method of claim 10, wherein the antimicrobial agent-bearing intervention device comprises an antimicrobial agent-bearing rod.

13. (Original) The infection management method of claim 12, wherein the antimicrobial agent-bearing rod comprises a flexible polymer rod.

14. (Original) The infection management method of claim 10, wherein the antimicrobial agent is iodine.

15. (Previously presented) The infection management method of claim 10, wherein a region of the catheter comprises a material which permits passage of the antimicrobial agent released from the antimicrobial agent-bearing intervention device from the catheter lumen to an outer surface of the catheter.

16. (Previously presented) The infection management method of claim 10, wherein the cap is adapted to seal a proximal end of the side-arm tube after the antimicrobial agent-bearing rod is inserted into the catheter lumen.

17. (Original) The infection management method of claim 16, wherein the cap has a threaded portion that cooperates with a threaded portion on the side-arm tube.

18. (Original) The infection management method of claim 16, wherein the cap is a stopper sized to frictionally engage and seal the proximal end of the side-arm tube.

19. (Previously presented) An anti-infection catheter, comprising

a main catheter tube with a lumen extending therethrough;
a side-arm tube extending laterally from a side of the main catheter tube, wherein
the side-arm tube is located in a region of the catheter which remains outside a patient's
body, and

a lumen through the side-arm tube communicates with the lumen of the main catheter
tube;

a one-way valve adapted to permit passage of an antimicrobial agent-bearing intervention
device between the side-arm tube lumen and the main catheter tube lumen while preventing fluid
flow from the main catheter tube lumen through the side-arm tube lumen, wherein the one-way
valve does not prevent fluid flow through the main catheter tube lumen; and

a cap coupled to the antimicrobial agent-bearing intervention device,
wherein the cap is configured so that a user can handle the antimicrobial agent-bearing
intervention device without directly contacting the antimicrobial agent-bearing intervention
device.

20. (Previously presented) The anti-infection catheter of claim 19, wherein the main
catheter tube comprises a catheter body and an extension joined to a proximal end of the catheter
body, and the side-arm tube extends laterally from the catheter extension.

21. (Previously presented) The infection management system of claim 1, wherein the
antimicrobial agent-bearing intervention device is configured to remain in the catheter lumen
during fluid flow through the catheter lumen.

22. (Previously presented) The infection management system of claim 21, wherein the fluid flow is associated with a hemodialysis procedure.

23. (Previously presented) The infection management method of claim 10, wherein the antimicrobial agent-bearing intervention device is configured to remain in the catheter lumen during fluid flow through the catheter lumen.

24. (Previously presented) The infection management method of claim 23, wherein the fluid flow is associated with a hemodialysis procedure.

25. (Previously presented) The anti-infection catheter of claim 19, wherein the antimicrobial agent-bearing intervention device is configured to remain in the main catheter tube lumen during fluid flow through the main catheter tube lumen.

26. (Previously presented) The anti-infection catheter of claim 25, wherein the fluid flow is associated with a hemodialysis procedure.

Applicant : Sharon Mi Lyn Tan
Serial No. : 10/690,436
Filed : October 22, 2003
Page : 15 of 16

Attorney's Docket No.: 01194-513001 / 03-045

Evidence Appendix

None.

Applicant : Sharon Mi Lyn Tan
Serial No. : 10/690,436
Filed : October 22, 2003
Page : 16 of 16

Attorney's Docket No.: 01194-513001 / 03-045

Related Proceedings Appendix

None.